

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK**

ATHENEX PHARMA SOLUTIONS, LLC and
ATHENEX PHARMACEUTICAL DIVISION,
LLC,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC., PAR
STERILE PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC,

Defendants.

Case No. 18-cv-00896-GWC

**PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC,
AND ENDO PAR INNOVATION COMPANY, LLC'S REPLY IN
SUPPORT OF THEIR MOTION TO DISMISS UNDER FED. R. CIV. P. 12(b)(1)**

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I. INTRODUCTION

Athenex incorrectly asserts that Par “ignores the totality of the circumstances test set forth by the Supreme Court.” There is no dispute the Supreme Court’s “all the circumstances” test applies here. *See* Par’s Opening Brief (ECF No. 10-7) at 14 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)). There is also no dispute that before Athenex filed its declaratory judgment complaint, Par had no knowledge of Athenex’s compounded vasopressin products and no knowledge of Athenex’s intention to make and sell those products.

A review of all the circumstances here undisputedly reveals no evidence of Par’s intent to enforce any patent against Athenex. Lacking any such evidence (which Athenex admits it must proffer), Athenex attempts to characterize a patchwork of unrelated events as a “threat of future injury.” But Athenex’s subjective speculation as to what Par might do has no place in the “all the circumstances” test under *MedImmune*. Athenex cannot contrive standing based on “fears of hypothetical future harm that is not certainly impending.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416 (2013). Athenex’s speculative fear of future harm fails to meet the objective standard for declaratory judgment. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008). Par respectfully requests that the Court grant Par’s motion to dismiss.

II. ARGUMENT

A. “All the Circumstances” Do Not Establish a Case or Controversy

1. Par’s Orange Book Listing Is Not an Affirmative Act of Intent to Enforce Its Patents

Athenex asserts that “[b]ecause the patents-in-suit are listed in the Orange Book as covering Vasostrict®, it naturally follows that any products that are alleged to be copies of Vasostrict® by Par, would also be, under Par’s position, covered by Par’s Orange Book-listed patents, and hence subject to a patent infringement suit by Par.” ECF No. 16 at 7. Athenex is

incorrect. Par's listing of the recited patents in the Orange Book and Par's assertion that certain compounded products would be "essentially a copy" of Vasostrict® under the Drug Quality and Security Act (DQSA) are not affirmative acts that establish an intent to enforce the patents against Athenex.

Par's mere listing of the subject patents in the Orange Book¹ is insufficient to show Par's intent to enforce those patents against potential infringers, including Athenex. The Federal Circuit explained this distinction as follows:

The listing of a patent in the Orange Book by an NDA filer is the result of a statutory requirement. Without more, Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned. The Orange Book is a listing of patents with respect to which claims of infringement "*could* be reasonably asserted..." 21 U.S.C. § 355(b)(1), (c)(2) (emphasis added). More is required for an actual controversy than the existence of an adversely held patent, however... We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (Fed. Cir. 2005), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (emphasis in original).

The Federal Circuit subsequently confirmed that listing a patent in the Orange Book may not on

¹ As set forth in the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act (FDCA), if an unexpired patent is listed in FDA's Orange Book as covering the approved drug product at issue, an applicant who seeks to market an FDA approved follow-on version of that drug product must certify either that it will not seek approval prior to the expiration of that patent, or that the patent is invalid or will not be infringed. *See* 21 U.S.C. §§ 355(b)(2)(A)(i)-(iv), (j)(2)(A)(vii)(I)-(IV). The follow-on applicant must provide notice to the patent owner explaining its invalidity or non-infringement rationale. *Id.* at §§ 355(b)(3), (j)(2)(B). The patent owner may file an infringement suit on all, some, or none of the listed patents. If the patent owner files suit within 45 days, FDA must refrain from approving the follow-on application for up to 30 months to allow that litigation to proceed. *See id.* at §§ 355(c)(3)(C), (j)(5)(B)(iii). Athenex readily acknowledges that none of these statutory provisions applies to its compounded vasopressin products, which are sold without any application for FDA approval, and Athenex did not provide any notice to Par. ECF No. 1 at ¶ 28.

its own support a case or controversy under the “all circumstances” standard for declaratory judgment jurisdiction. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007). Indeed, it is not uncommon for patent holders, for various reasons, not to sue generic applicants on all of the listed patents. *See, e.g., Medeva Pharma Suisse A.G. v. Par Pharm., Inc.*, 774 F. Supp. 2d 691, 699 (D.N.J. 2011), *aff’d*, 461 F. App’x 933 (Fed. Cir. 2012) (patentee brought suit on one of two Orange Book patents for the drug Asacol[®]). The patent holder may decide not to sue on any of the patents. *See* 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5). Athenex’s reliance on Par’s listing of the patents in the Orange Book is merely an allegation that Par’s patents exist. The existence of these patents, without more, does not create a case of actual controversy. *AIDS Healthcare Found., Inc. v. Gilead Scis., Inc.*, 890 F.3d 986, 991 (Fed. Cir. 2018).

Athenex also relies on Par’s legal positions in litigation with FDA that certain compounded vasopressin products are “essentially a copy” of Vasopressin[®]. ECF No. 16 at Section II.C. But Par’s statements do not evince an affirmative act of intent to enforce Par’s Orange Book patents against Athenex. On the contrary, Par’s use of the phrase “essentially a copy” in those proceedings refers to statutory requirements for compounded drugs under the DQSA—and has nothing to do with patent infringement. Par asserted that certain compounded vasopressin products are ineligible for compounding under 503B, because such compounding would result in “essentially a copy” of an FDA-approved drug, violating the requirements of section 503B of DQSA. Section 503B defines the phrase “essentially a copy of an approved drug” as a drug that has not been changed in a way “that produces for an individual patient a clinical difference ... between the compounded drug and the comparable approved drug.” 21 U.S.C. § 353b(d)(2)(B). Par’s legal position that compounded vasopressin meets this

definition—and therefore cannot be legally sold without obtaining FDA approval—is irrelevant to whether Par intends to enforce its Orange Book patents against Athenex.

Indeed, the Federal Circuit has squarely rejected efforts to conflate FDA standards (e.g., for bioequivalence) with issues of patent infringement. *See, e.g., Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 n.3 (Fed. Cir. 2008) (“FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries”); *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009) (bioequivalence is a “regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes” and does not mean *per se* infringement). For the same reason, Athenex’s reliance on Par’s statements that QuVa’s compounded vasopressin product is—from an FDA perspective—a “substitute,” “follow-on,” or “nearly identical” to Vasostriect[®] is irrelevant to whether Par intends to enforce patents against Athenex. *See Teva*, 395 F.3d at 1333; *Novartis*, 482 F.3d at 1342. In the context of litigation about FDA’s implementation of the DQSA, Par’s assertions mean only that certain compounded vasopressin products do not meet the Section 503B requirements for exemption from the ordinary FDA approval process under the Hatch-Waxman Act. *See* ECF No. 16 at 16 (“Par’s position is that compounded vasopressin products... should abide by the Hatch-Waxman scheme”).

In addition, Par’s general statements that it will “vigorously defend and protect its substantial investment in its proprietary products” (ECF No. 16 at 7) are likewise irrelevant to whether Par intends to enforce its patents against Athenex. General statements about enforcing patent rights do not suffice to show an imminent threat of litigation, especially when made before knowledge of the declaratory judgment plaintiff’s activities. *Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Res.*, No. 14 CIV. 2256(PAC), 2014 WL 6765996, at *4

(S.D.N.Y. Dec. 1, 2014); *Impax Labs., Inc. v. Medicis Pharm. Corp.*, No. C-08-0253 MMC, 2008 WL 1767044, at *3 (N.D. Cal. Apr. 16, 2008).

In sum, Par's conduct does not reflect a "preparedness and a willingness to enforce its patent rights" against Athenex. *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1332 (Fed. Cir. 2014) (citation omitted).

2. Par Did Not Engage in Any Affirmative Acts of Patent Enforcement against Athenex as an Unknown Compounder

Athenex goes so far as to argue that Par intended to enforce its patents against Athenex, even before Par was aware of Athenex's compounded vasopressin products. But the case law Athenex cites does not support such an expansion of declaratory judgment jurisdiction. None of the cases Athenex found jurisdiction where the identity of the plaintiff was unknown prior to the declaratory judgment complaint.

For example, Athenex relies heavily on *Asia Vital Components Co. v. Asetek Danmark A/S*, 837 F.3d 1249 (Fed. Cir. 2016), for its argument that declaratory judgment jurisdiction does not require knowledge of the specific infringing product. ECF No. 16 at 19. But in *Asia Vital*, the identity of the accused infringer was plainly known. What was unknown was the exact infringing product, but the defendant engaged in numerous affirmative acts showing intent to enforce its patents against the plaintiff. In fact, the defendant repeatedly communicated with the plaintiff about the plaintiff's infringing activity and sent plaintiff a demand letter referencing a product similar to the actual infringing product. *Asia Vital*, 837 F.3d at 1253. Defendant also rehashed the volatile relationship between the parties, declined licensing options to the plaintiff, accused the plaintiff of selling other infringing products in the United States, and warned the plaintiff specifically about enforcing its patents. *Id.* Defendant also threatened the plaintiff's customers about infringement. *Id.* at 1254. The Federal Circuit found that the question of

declaratory judgment jurisdiction did not turn on the patentee's knowledge of the specific products at issue, but that under all the circumstances, the patentee's actions demonstrated an intent to enforce a patent. *Id.*

Athenex's other cited cases are also misplaced, as in each of those cases the identity of the accused infringer was known, and the parties had directly engaged in communications regarding patent infringement before suit was brought. *See Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 733-734 (Fed. Cir. 1988) (defendant sent a cease and desist letter to plaintiff, warned plaintiff's customers of patent infringement, and submitted a proposed finding in another lawsuit that plaintiff infringed the patent); *Danisco*, 744 F.3d at 1331 (defendant alleged that plaintiff's product would infringe even before the patent issued and the parties "have plainly been at war over patents"); *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1358 (Fed. Cir. 2013) (defendant had already asserted that plaintiff infringed closely related patents covering the same technology); *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (defendant warned plaintiff in a letter that a breach of the contract would constitute induced infringement of defendant's patent, and that defendant would act vigorously to protect its rights in that event); *Arris Grp., Inc. v. British Telecommunc'ns PLC*, 639 F.3d 1368, 1378-79 (Fed. Cir. 2011) (plaintiff and defendant engaged in licensing negotiations and exchanged patent infringement contentions).

Here, it is undisputed that Par did not know Athenex's identity and Par did not direct any affirmative acts of patent enforcement towards Athenex before Athenex filed its complaint. Jurisdiction therefore does not exist. *Allied Mineral Prod., Inc. v. OSMI, Inc.*, 870 F.3d 1337, 1340 (Fed. Cir. 2017) (no subject matter jurisdiction where defendant "has not directed any

actions towards [plaintiff]” and there was no direct communication between defendant and plaintiff).

Contrary to Athenex’s assertion, it was Par—not Athenex—who had to “stand by and wait to be sued.” ECF No. 16 at 20. Athenex affirmatively concealed itself from the public, and Par, as an “undisclosed compounder.” It sought to pave the way to market its compounded vasopressin products, while ensuring that any entity that might have wished to engage Athenex regarding its actions could not, as Athenex concealed its identity. Athenex’s surreptitious actions culminated in the filing of this lawsuit—on the same day it chose to reveal its identity to the world. Declaratory judgment jurisdiction simply does not exist here, where Par did not even have knowledge of Athenex prior to this lawsuit. *See Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1380 (Fed. Cir. 2010) (patentee’s knowledge about defendant’s FDA filing insufficient to create a case or controversy).

3. Athenex’s Speculation and Reliance on After-Arising Events Do Not Establish Jurisdiction

Having hidden its identity and plans from Par, which precluded Par’s engagement with Athenex prior to the declaratory judgment complaint, Athenex now relies on its own speculation and claimed subjective fear of suit, citing to statements made *after* it filed the complaint. Athenex’s speculation and reliance on after-arising events do not establish jurisdiction here for multiple reasons.

Athenex speculates that after listing its patents in the Orange Book, the “next logical step would be Par asserting its patents against Athenex.” ECF No. 16 at 2. The only basis for Athenex’s guess is its own assumption of a future patent infringement lawsuit. *See, e.g., id.* at 17 (“Par’s past conduct *suggests* that had Par known that Athenex was the unidentified compounder referenced in its FDA complaint in October of 2017, it would already have sued Athenex for

patent infringement.”) (emphasis added). In fact, Athenex relies on QuVa’s—not Par’s—counterclaims for a declaration of noninfringement of Par’s Orange Book Patents, again speculating, this time about what Par’s answers to the counterclaims might be. *Id.* at 8 (“When Par answers QuVa’s counterclaims, it will undoubtedly assert that QuVa’s compounded vasopressin product infringes the patents.”). QuVa’s counterclaims have nothing to do with Par’s intent to enforce its patents against QuVa, let alone Athenex. Athenex admits that Par has not yet answered QuVa’s counterclaims. *Id.* Par’s suits against other competitors likewise do not show an intent to enforce its patents against Athenex. *See Innovative Therapies*, 599 F.3d at 1382 (holding that “the fact that [defendant] had filed infringement suits against other parties for other products does not, in the absence of any act directed toward [plaintiff], meet the minimum standard discussed in *MedImmune*.”).

In the words of the Supreme Court, Athenex cannot manufacture standing “based on [its] fears of hypothetical future harm that is not certainly impending.” *Clapper*, 568 U.S. at 416. Declaratory judgment jurisdiction is based on “an objective standard that cannot be met by a purely subjective or speculative fear of future harm.” *Prasco*, 537 F.3d at 1339. Athenex’s own speculation is simply irrelevant to support jurisdiction.

To support its speculation, Athenex also cites to numerous statements Par made in the FDA suit after the complaint was filed in this action. ECF No. 16 at 12-13 (admitting the statements were “made after the complaint in this case was filed”). But it is hornbook law that a declaratory judgment plaintiff must plead facts sufficient to establish jurisdiction at the time of the complaint. Post-complaint facts cannot create jurisdiction. *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 906 (Fed. Cir. 2014) (citing *Innovative Therapies*, 599 F.3d at 1383-84).

Even if these post-complaint facts were to be considered, none of Par's statements manifest any intent or threat to sue Athenex for patent infringement.

B. Athenex's Alleged Threat of Future Injury Is Not Redressable by this Lawsuit

Athenex admits that its redress is with the FDA. ECF No. 16 at 24 ("Athenex may still bring suit challenging FDA's determination"). This makes sense because the only injury that Athenex has alleged is caused by the FDA, not Par. ECF No. 17, Ex. B. at 8 ("If the FDA Guidance were invalidated or vasopressin were removed from the Category 1 List, Athenex would be forced to stop selling its vasopressin products."). Athenex has not alleged any injury caused by Par; indeed Par's Orange Book patents did not stop Athenex from entering the market when it filed its declaratory judgment complaint.

Athenex asserts that "creating a barrier to the regulatory approval of a product that is necessary for marketing" is one way a declaratory judgment plaintiff can show injury. ECF No. 16 at 17 (citing *Prasco*, 537 F.3d at 1339). But no regulatory barrier is involved in Athenex's patent complaint—Athenex entered the market at the same time it filed its complaint without seeking FDA approval of its drug under the Hatch-Waxman Act. Regardless, Athenex's reliance on *Prasco* is inapposite, because the "regulatory barrier" in *Prasco* was the stay of FDA approval of an ANDA in the Hatch-Waxman framework—a barrier Athenex asserts it is not subject to. *Prasco*, 537 F.3d at 1339 (citing *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008)). To the extent FDA has caused an injury to Athenex, Athenex has already intervened in the FDA suit. Other than its own subjective fear, Athenex fails to show any injury caused by Par that is redressable by this Court. *Id.*

III. CONCLUSION

For the foregoing reasons, the Court should grant Par's Motion to Dismiss for lack of subject matter jurisdiction.

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HAGERTY & BRADY

By: s/ Michael A. Brady
MICHAEL A. BRADY, ESQ.
Attorneys for Defendants PAR
PHARMACEUTICAL, INC., PAR STERILE
PRODUCTS, LLC, and ENDO PAR
INNOVATION COMPANY, LLC
69 Delaware Avenue, Suite 1010
Buffalo, NY 14202-3875
Telephone: (716) 856-9443
Fax: (716) 856-0511

Of Counsel:

Daniel G. Brown
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022-4834
Telephone: (212) 906-1200
Fax: (212) 751-8464

Jennifer Koh
Yi Sun
LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
Telephone: (858) 523-5400
Fax: (858) 523-5450